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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF CHRISTOPHER S. MORRIS, M.D.**

Pursuant to Federal Rule of Evidence 702, Plaintiffs move this Court for an order excluding the opinions and testimony of Defendants' expert witness, Christopher S. Morris, M.D., because his methods, opinions and testimony do not comport with the legal requirements of an expert witness. Plaintiffs' motion is supported by the Memorandum of Law set out below and the declaration of counsel and exhibits attached thereto.

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MEMORANDUM OF LAW

Plaintiffs move to exclude the opinions and testimony of Defendant Bard's expert Christopher S. Morris, M.D., who intends to offer expert opinions in the medical monitoring class action (*Barraza, et al. v. Bard*) in addition to the bellwether matters before this Court.[1]

Even setting aside his undeniable bias as a longtime paid consultant for Bard,[2] in forming his opinions, Dr. Morris selectively ignored FDA recommendations, ignored peer-reviewed studies, ignored relevant data, and offers sweeping, unsupported opinions. He failed to employ a foundation or methodology that meets Rule 702's reliability standards. His opinions should therefore be rejected as unreliable and of no assistance to the trier of fact.

I. INTRODUCTION AND BRIEF SUMMARY OF MOTION

Christopher S. Morris, M.D. is an interventional radiologist who is being offered as an expert by Bard in both the Bard IVC Filter MDL and the *Barraza* class action. In the class action, he primarily seeks to dispute the validity of Plaintiffs' proposed follow-up protocol for medical monitoring. [redacted]

[1] Dr. Morris submitted separate expert reports in both the Bard IVC Filter MDL and the *Barraza* class action. Dr. Morris submitted a report in the class action on March 16, 2017, and a supplemental report on May 26, 2017 (hereinafter collectively "Class Rep.") (Exs. 1 and 2). Dr. Morris submitted his report in the MDL, entitled "Bard IVC Filter Multi-District Litigation Expert Report on April 13, 2017 (hereinafter "MDL Rep.") (Ex. 3). Dr. Morris's deposition was taken on July 25, 2017. (Transcript is attached as Ex. 4). Unless otherwise noted, all exhibits are attached to the accompanying Declaration of Wendy R. Fleishman.

[2] [redacted]

[redacted]

Dr. Morris intends to offer generalized, often unsupported opinions, to challenge Plaintiffs' proposed monitoring protocol, a protocol that includes medical imaging as a tool to assist in finding and treating IVC filter complications. Dr. Morris' opinions should be precluded pursuant to Fed. R. Evid. 702 because he has not applied reliable principles and methods. Instead, he rests his conclusions upon his own subjective assessments and intuition. Specifically, the Court should exclude the following opinions Dr. Morris intends to offer:

[redacted]

This opinion should be excluded because it is based on his "*ipse dixit,*" subjective opinions. [redacted]

[redacted] This opinion should be excluded because it is based on "*ipse dixit,*" and fails to acknowledge any of the relevant

literature recognizing that pre-retrieval medical imaging is a standard component of any IVC filter patient follow-up protocol.

[redacted] This opinion should be excluded because it is based only on Dr. Morris's *ipse dixit* and fails to consider the regulatory authority and medical community's recognition of complication-risk being the primary purpose of patient follow-up.

[redacted] This opinion should be excluded because it is based only on Dr. Morris's *ipse dixit*, and ignores the peer-reviewed literature recognizing the elevated risk of complications for patients with Bard IVC filters and that establish that the risk of complications increases the longer the filters remain indwelling in patients. His opinion is also unreliable because he fails to acknowledge the availability of modern retrieval techniques, reported in the peer-reviewed literature, for retrievals of filters that have been in place for extended periods of time.[3]

II. STANDARD OF REVIEW

An expert's opinion is not reliable and should be excluded where, as here, the expert has not applied reliable principles and methods, but instead has rested his conclusions upon mere intuition or general claims of expertise. *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1067-68 (C.D. Cal. 2013) (excluding expert's opinion that was "not based on a reliable foundation or methodology" but instead amounted solely to expert's "*ipse dixit*");

[3] Dr. Morris only performs percutaneous filter retrievals, using a hook through the jugular vessel or femoral artery to remove the filter. Ex. 4, Morris Dep. 120:5-121:8. His practice does not perform any of the open percutaneous procedures or open surgeries that other interventional radiologists and vascular surgeons safely utilize for filter retrievals. *Id.*

see also Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) (expert opinions cannot be "connected to existing data only by the ipse dixit of the expert"). The duty falls squarely upon the district court to "act as a 'gatekeeper' to exclude junk science" that does not meet Rule 702's reliability standards. *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011). The court's gatekeeping function requires more than "taking the expert's word for it." Fed. R. Evid. 702-2000 Committee Notes (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (the "experts' qualifications, their conclusions and their assurances of reliability" are "not enough" under *Daubert*)).

When deciding whether to exclude opinion testimony under *Daubert*, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. If the testimony is not based on "pre-litigation" research or if the expert's research has not been subjected to peer review, then the expert must explain precisely how he went about reaching his conclusions and point to some objective source—a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like—to show that he has followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in his field. *Id.* at 1318–19 (citing *United States v. Rincon*, 28 F.3d 921, 924 (9th Cir.1994)); *see also Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 597 (9th Cir. 1996). The proponent of the evidence must prove its admissibility by a preponderance of proof. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 n.10 (1993).

III. ARGUMENT

A. [redacted]

A key issue in all of these Bard IVC filter cases before the Court is whether the Bard retrievable filters have an unacceptably high fracture rate and overall complication rate (fracture, migration, perforation, and tilt). Plaintiffs' experts' reports demonstrate that Bard's retrievable filters do indeed have elevated and unacceptably high fracture rates; those opinions are based upon multiple lines of evidence, including peer-reviewed

published studies, internal Bard assessments, adverse event reporting disparities, and expert engineering assessments. [redacted] As explained below, Dr. Morris's outcome-driven and selective review of the literature does not pass muster under Rule 702 or *Daubert*.

1. [redacted] When an expert "reaches his opinion by first identifying his conclusion ... and then cherry-picking observational studies that support his conclusion," that opinion "does not reflect scientific knowledge, is not derived by the scientific method, and is not 'good science.'" *See In re Bextra & Celebrex Mktg. Sales Practices & Prods. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007). [redacted] "spread far too thin to reliably support expert scientific testimony." *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 289 F. Supp. 2d 1230, 1250 (W.D. Wash. 2003) (*citing Joiner*, 522 U.S. at 146) (court may conclude that there is simply too great an analytical gap between the data and the opinion proffered).

[redacted]

[redacted] These studies, such as those by An, *et al.*[4] (Ex. 7) and Tam, *et al.*[5] (Ex. 8), have estimated that the fracture rate of some Bard IVC filters are 40% at five years. *Id.* at 184:9-19; 188:13-19. [redacted] For instance, the Nicholson study (Ex. 9) found 25% filter fracture rates for patients with Recovery filters and life-threatening complications associated with fractures.[6] [redacted]

[4] Tianzhi An, MD, et al., *Prevalence and Clinical Consequences of Fracture and Fragment Migration of the Bard G2 Filter: Imaging and Clinical Follow-up in 684 Implantations*, 25 J. Vasc. Interv. Radiol. 941, 941 (June 2014) (2014 Cleveland Clinic study reporting 38% fracture rate for Bard G2 devices at 60 months post-implantation).

[5] Matthew D. Tam, MD, et al., *Fracture and Distant Migration of the Bard Recovery Filter: A Retrospective Review of 363 Implantations for Potentially Life-Threatening Complications*, 23 J. Vasc. Interv. Radiol. 199, 199 (Feb. 2012) (Cleveland Clinic study concluding that Recovery had a "5.5-year fracture risk of 40%").

[6] William Nicholson, MD et al., *Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade*, Arch. Intern. Med., at E3 (Aug. 9, 2010) (finding 25% filter fracture rate for patients for Recovery, and life-threatening complications associated with fracture, with 71% of that group having at least one fragment embolize to the right ventricle of the heart, including one with hemorrhagic pericardial effusion requiring emergency surgery, and another who experienced sudden death at home).

[7] *See, e.g.*, Ex. 10, Jeffrey E. Hull, MD et al., *Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration*, 20 J. Vasc. Interv. Radiol. 52, 55 (Jan. 2009) (reporting that at long-term follow-up 100% of 14 Recovery patients evaluated had filter arm perforations, 36% had leg perforations, and 21% had fractures associated with migration); Ex. 11, Steven E. Deso, MD, et al., *Evidence-Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type*, 33 Semin. Interv. Radiol. 93, 93, 96 (2016) (evidence based evaluation of IVC filter complications conducted at Stanford Medical Center of 23 IVC filter design types, concluding that "Bard filters were associated with the highest reported risks of fracture (40%)," and a fracture

[redacted] But the high fracture rates of Bard filters found in studies such as those by An,[9] Tam,[10] Nicholson,[11] and Hull[12] were based only on a review of Bard filters, not a

rate for G2, G2X, Eclipse, and Meridian devices at 60 months of 38%).

[8] Kalva et al., *"Recovery" Vena Cava Filter: Experience in 96 Patients*, 29 Cardiovasc. Interv. Radiol. 559, 564 (2006).

[9] *See* Ex. 7, An, *supra* note 4 (38% fracture rate).

[10] *See* Ex. 8, Tam, *supra* note 5 (5.5-year fracture risk of 40%).

[11] *See* Ex. 9, Nicholson, *supra* note 6 (25% filter fracture rate).

[12] *See* Ex. 10, Hull, *supra* note 7 (21% fracture rate associated with migration).

comparison with other filters. [redacted] Dr. Morris first identified his conclusion, and then rejected the findings of multiple peer-reviewed studies that were inconsistent with his hypothetical conclusion, based on subjective, *ipse dixit* assessments, and then, in order to justify the opinion he sought to supply, he "cherry-picked" observational studies that support that conclusion. *See In re Bextra*, 524 F. Supp. 2d at 1176. His opinion does not amount to good science or reliable methodology, and should therefore be excluded.

2. Dr. Morris Refuses to Consider Bard's Internal Data in Formulating his Opinions.

Dr. Morris also rendered his opinions about the safety and efficacy of Bard's filters without evaluating the necessary data to reach this conclusion. Instead, he purposely avoided reviewing any of Bard's internal data in order to reach his opinions. Courts often reject this type of "litigation selection bias." *In re Countrywide Fin. Corp. Mortgage-Backed Sec. Litig.*, 984 F. Supp. 2d 1021, 1040 (C.D. Cal. 2013) (finding underlying data insufficient such that expert sampling methodology could not be reliably relied upon); *In re Bextra*, 524 F.Supp.2d 1166, 1176 (N.D.Cal.2007) (rejecting expert testimony that "cherry-pick[ed]" studies to analyze in support of the expert's conclusion).

[redacted]

[redacted]

But Bard's internal documents provide crucial information to properly evaluate its filters. [redacted]

All of this information serves an important basis for determining the overall complication rates of Bard's filters, relative safety, and the necessity of a monitoring protocol. It also serves as a necessary aspect for the formation of any expert opinion as to the safety and effectiveness of the filters. In testifying on behalf of Bard, Dr. Morris had the opportunity to access Bard's full range of internal information. Without considering

this data, the studies, and information relied upon by Plaintiffs' experts, Dr. Morris cannot reliably criticize their opinions or opine on the safety of Bard's filters. *See In re Toyota*, 978 F. Supp. 2d at 1067-68 (excluding expert's opinion that was "not based on a reliable foundation or methodology" but instead amounted solely to expert's "ipse dixit"). Dr. Morris's speculative and unreliable opinions should be excluded because the opinions are based on his subjective, *ipse dixit* opinions, his reliance on cherry-picked information, his disregard of Bard's internal data and assessments, and his decision to turn a blind eye to the short-term follow-up limitations in studies he did rely upon which found low complication rates.

B. [redacted]

Plaintiffs and their experts have suggested that the use of medical imaging is necessary for patients receiving follow-up to help determine the status of theirs filters, assist doctors in treatment decisions, in order to prevent or treat complications.

[redacted] His opinions, however, lack any basis and are controverted by both the literature and by Bard's own recommendations.

1. <u>The Literature Suggests that Pre-Retrieval Medical Imaging is a Necessary Component of a Follow-up Program.</u>

[redacted]

forth the steps used to reach the conclusion that the research [upon which he relies] is applicable," and demonstrate that his "reasoning between steps in a theory [is] based on objective, verifiable evidence and scientific methodology of the kind traditionally used by

experts in the field." *See Domingo v. T.K.*, 289 F.3d 600, 606-07 (9th Cir. 2002). In the absence of independent research or peer reviewed studies, experts must explain the process by which they reach their conclusions and identify some type of objective source demonstrating adherence to the scientific method. *See In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 289 F. Supp. 2d at 1238.

[redacted] over the years, the Society of Interventional Radiologists ("SIR") has published multiple "Reporting Standards for Inferior Vena Cava Filter Placement and Patient Follow-up." *See, e.g.*, 2003,[13] 2005,[14] and 2009[15] SIR Patient Follow Reporting Standards. These guidelines recommend "minimum objective testing" of the filter during follow-up, which includes "imaging of vena cava prior to retrieval" to determine its stability and position. *See, e.g.*, Ex. 18 at 429; Ex. 19 at 442; Ex. 20 at 375. [redacted]

In fact, *Bard* relies on the same standards in its own filters' Instructions for Use ("IFUs"). *See* Ex. 17 at 3 (Bard Denali IFU citing to Society of Interventional Radiologists), at 3; *see also* Ex. 3, MDL Rep. 7; Ex. 1, Class Rep. 6. The IFUs reiterate the recommendation for follow-up procedures to physicians, [redacted]

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[13] Ex. 18, The Participants in the Vena Caval Filter Consensus Conference, *Recommended Reporting Standards for Vena Caval Filter Placement and Patient Follow-U*p, 14 J. Vasc. Interv. Radiol. 427 (2003).

[14] Ex. 19, Steven F. Millward FRCPC et al., *Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters*, 16 J. Vasc. Interv. Radiol. 441 (2005).

[15] Ex 20, Steven F. Millward FRCPC et al., *Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters*, 20 J. Vasc. Interv. Radiol. S374 (2009).

[redacted]—they are intended to be instructions for physicians who put these IVC filters into patients as part of their practice.

There is also is strong support from authoritative groups and the medical literature that imaging is a critical part of the follow-up process. For example, Hull, *et al.* (2009)[16] state: "We are recommending imaging with abdominal CT to screen for perforation, fracture, and migration in patients with a Recovery filter in place." Duffet, *et al.* (2016)[17] wrote: "In patients where the filter remains in place, close follow-up to assess removal and screening for filter complications, such as strut fracture, embolization and IVC occlusion, should be considered." And Kuo, *et al.* (2013)[18] wrote that patients with implanted filters "should at least be closely monitored for complications that could then be treated at centers with appropriate expertise." In 2016, the Society of Interventional Radiology and American College of Radiology issued a joint practice parameter, which calls for patients to be "clinically reassessed" for "mechanical failure" of the filters.[19] These are just a few examples. [redacted]

2. [redacted]

[16] Ex. 10, Hull, *supra* note 6.

[17] Ex. 21, L. Duffett, MD, *Inferior Vena Cava Filters*, 15 J. Thrombosis & Haemostasis 3, 9 (2017).

[18] Ex. 22, William T. Kuo, MD et al., *Complex Retrieval of Fractured, Embedded, and Penetrating Inferior Vena Cava Filters: A Prospective Study with Histologic and Electron Microscopic Analysis*, 24 J. Vasc. Interv. Radiol. 622, 629 (May 2013).

[19] Ex. 23, ACR–SIR–SPR Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism, at 2 (2016).

[redacted] The relevant regulatory authorities specifically identify potential adverse events as the primary reason that they recommend follow-up in the first place. For example, in May 2014, the FDA announced:

> **Summary of Problem and Scope:**
> The FDA has received reports of adverse events and product problems associated with IVC filters. … The FDA is concerned that retrievable IVC filters, when placed for a short-term risk of pulmonary embolism, are not always removed once the risk subsides.
>
> **Recommendations/Actions:**
> The FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from pulmonary embolism is no longer needed.
>
> The FDA encourages all physicians involved in the treatment and follow-up of patients receiving IVC filters to consider the risks and benefits of filter removal for each patient.

Ex. 24, May 6, 2014 FDA Safety Communication.

In July of 2016, Health Canada announced:

> Serious complications have been reported in patients implanted with an IVC filter, including caval perforation, caval thrombosis, filter fracture and fragment embolization, intracardiac migration, cardiac perforation, cardiac

> tamponade, and death. Many of these complications occurred with long-term (greater than 30 days) filter implantation.
> …
> Health Canada encourages each hospital to identify all patients who have a retrievable IVC filter placed and to develop a formal strategy to assess these patients for filter removal.

Ex. 25, July 25, 2016, Health Canada Product Safety Alert.

[redacted] For example, imaging during follow-up can help determine if patients have embedded filter tips, tilted filters, or filters perforating the vena cava.[21] [redacted] Studies have found that in these situations, pre-retrieval imaging can be especially useful to help doctors identify whether complicated retrieval procedures are necessary or otherwise help tailor the retrieval approach.[22]

[redacted]

[20] Ex. 7, An, *supra* note 4, at 946 ("[T]he estimated fracture risk progressively increased with longer filter dwell times."); Ex. 10, Hull, *supra* note 7 ("[F]ilter arm perforation progressed from 56% of patients … to 100% …. "[F]ractures progressed from an incidence of zero to 21%"); Ex. 21, Kuo, *supra* note 10, at 56-57 ("The risk of filter fracture increases after 408 days."); Ex. 9, *Nicholson*, supra note 6, at E2 ("[I]ncidence of filter fracture would be directly proportional to the time that the filter is allowed to dwell in the patient after implantation."); Ex. 11, Deso, *supra* note 7, at 96 ("[C]omplications tend to increase after longer dwell times."); Ex. 26, Vijay et al., *Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: incidence, Clinical Consequences, and Outcomes of Removal Attempts*, 23 J. Vasc. Interv. Radiol. 188, 194 (2012) ("The incidence of fractured increased with longer filter dwell times."); Ex. 27, Dinglasan et al., *Complicated Inferior Vena Cava Retrievals: Associated Factors Identified at Preretrieval CT*, 266 Radiology 1, 347, 353 (Jan 2013) ("Increased dwell time was also shown to be associated with complicated filter retrieval, with risk increased by 2.3 times with a dwell time longer than 180 days.").

[21] *See, e.g.*, Ex. 27, Dinglasan, *supra* note 20.

[22] *Id.*

[redacted]

His testimony is "too speculative" and does not constitute "expert opinion that can 'assist the trier of fact ...'" *See Brighton Collectibles, Inc. v. Renaissance Grp. Int'l*, No. 06-CV- 115 H(POR), 2008 WL 5500659, at *4 (S.D. Cal. May 13, 2008) (citation omitted). His opinions and critiques regarding the decision to image the filters should not be permitted.

C. [redacted]

[redacted] Upon follow-up imaging, it may be determined that a filter that has long been in place has embedded tips, tilted, or perforated of the vena cava. Although these factors may make retrieval more difficult, imaging can help doctors tailor the retrieval approach. The literature suggests that these patients can also be referred to tertiary care centers that specialize in retrieving especially difficult to retrieve filters. [23] [redacted] His opinion should therefore be excluded.

IV. CONCLUSION

As set forth above, Dr. Morris's opinions as outlined above should not be permitted at trial because these opinions are not supported by reliable scientific evidence or based upon proper methodology, are speculative and unreliable, and will tend to confuse the jury rather than assist the triers of fact in understanding the evidence presented to them.

RESPECTFULLY SUBMITTED this 24th day of August, 2017.

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[23] *See* Ex. 27, Dinglasan, *supra* note 20.

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of August, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti